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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/903,640      | 07/11/2001  | Avi Ashkenazi        | 10466/85            | 3104             |

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/903,640

Applicant(s)

ASHKENAZI ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 39-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 39-51 are pending in the present application. This Office action is in response to Paper No. 14, filed 17 March 2003.

#### ***Response to Arguments***

Claims 39-51 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

Applicant has asserted and provided a declaration by Audrey D. Goddard, Ph.D. in support of the assertion that the gene amplification data provided in the specification are adequate to establish a specific, substantial and credible utility for the claimed PRO343 polypeptide. Applicant points to Example 92 in the specification wherein gene amplification data using TaqMan PCR show that the gene encoding PRO343 showed 1.15-3.82 fold gene amplification in some lung and colon tumors. The declaration of Dr. Goddard in paragraph 6 and paragraph 7 assert that TaqMan PCR has been widely used in the characterization of genes and is sensitive enough to detect at least a two-fold increase in gene copy number. Paragraph 7 of the declaration further states that it is the opinion of Dr. Goddard that at least a two-fold increase in gene copy number in a tumor sample relative to a normal sample is useful as a diagnostic marker for the presence of a tumor. Although a specific, substantial and credible utility may exist for the polynucleotide encoding PRO343 to detect cancer cells due to increased copy number, the present claims are drawn to the polypeptide PRO343, not the polynucleotide. The increased copy number of DNA does not provide a readily apparent use for the polypeptide, for which there is no information regarding level of expression, activity, or role in cancer. As

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such neither Applicant's arguments nor the declaration by Dr. Goddard provide a specific, credible or substantial utility for the claimed polypeptides.

Claims 39-51 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has argued in response to the pending rejection under the written description requirement of 35 U.S.C. 112, first paragraph that the claims as amended recite that the polypeptides are associated with the formation or growth of lung or colon tumor. According to Applicant, this newly added limitation provides distinguishing characteristics or features such that one of skill in the art would reasonably conclude that Applicant had possession of the claimed polypeptides. MPEP 2163(I)(A) clearly states:

A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

A generic statement . . . without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function." See *University of California v. Eli Lilly and co.* 119 F.3d 1559, 43 USPQ2d 1398 (1997). The limitation that the polypeptide is associated with the formation of lung or colon tumors is not a sufficient identifying characteristic to overcome the instant rejection. Applicant has not specifically defined any of the proteins having homology with PRO343 that fall within the broad genus claimed nor does Applicant describe any structural characteristics commonly possessed by

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members of the genus such that one of skill in the art would recognize that Applicant was in possession of the full breadth of the invention claimed. Thus, the written description requirement is not satisfied.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves  
August 28, 2003



JAMES KETTER  
PRIMARY EXAMINER